REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated December 13, 2005 are respectfully requested.

I. Amendments

Claim 1 is amended in the preamble to use Markush language, as suggested by the Examiner. Claim 1 is also amended for clarity in the first recited method step.

II. Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-7 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner found claim 1 to be indefinite in that it is not clear what degree of increase in OAS levels would be needed to be considered a "measurable" increase. This rejection is traversed in view of the following.

The Examiner is directed to paragraph [0045] of the application where the term "measurable increase in blood OAS level" is defined.

The M.P.E.P. provides that "[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure....". M.P.E.P. § 2173.02. Indeed, the it has been held that "a claim which is clear to one ordinarily skilled in the art when read in light of the specification, does not fail for indefiniteness." *Allan Archery, Inc. v. Browning Manufacturing Co.*, 819 F.2d 1087, 2 USPQ2d 1490 (Fed. Cir. 1987).

Accordingly, Applicants submit that the term "measureable" is clear when read in light of the specification. Thus, withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

III. Rejections Under 35 U.S.C. § 103

Claims 1-7 were rejected under 35 U.S.C. §103 as allegedly obvious over Soos *et al.*, U.S. Patent No. 6,372,206 (hereinafter "Soos"). This rejection is respectfully traversed for the following reasons.

A. The Present Claims

The claimed method relates to treating a condition responsive to interferon tau therapy, wherein the condition is selected from an autoimmune condition, cancer, or a viral infection, in a human subject. The method includes orally administering interferon-tau to the intestinal tract of the subject in an amount effective to produce a measurable increase in the subject's blood 2', 5'-oligoadenylate synthetase (OAS) level, relative to the blood OAS level in the subject in the absence of interferon-tau administration, wherein said amount of interferon-tau is at least about 4.9×10^8 Units/day, and continuing to administer interferon-tau to the intestinal tract of the subject in such effective amount, on a regular basis of at least several times per week, for a period of at least one month, independent of changes in the subject's blood OAS level.

B. The Applied Art

Soos describes oral administration of interferon-tau for the treatment of a variety of conditions.

C. Analysis

It is the Examiner's position that although Soos does not discuss the changes in blood OAS level following administration of interferon-tau, changes in blood OAS is inherent to the administration of interferon-tau and thus would be expected to change with the administration of interferon-tau.

The legal standard to establish inherency requires that the prior art in question necessarily produces the newly claimed effects, and that a person skilled in the art would recognized that the newly claimed effects were necessarily achieved. (*Continental Can Co. USA, Inc. v. Monsanto Co,* 948 F. 2d. 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. (*In re Robertson,* 169 F. 3d 743, 49 USPQ2d 1949 (Fed Cir. 1999, quoting from *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA, 1981).

Applicants have established that not all doses of interferon-tau produce a measurable increase in blood OAS levels in human subjects. As noted in the

application in paragraph [0079], humans treated with orally administered interferon-tau show a varied response, with some persons producing a measurable increase in OAS blood level and other persons not producing a measurable increase in OAS. Because of the variability in response, the effect of an increased blood OAS level following oral administration of interferon-tau is not necessarily achieved, and therefore not inherent to administration of interferon-tau.

As noted above, the method set forth in claim 1 recites oral administration of interferon-tau at a dose of at least about 4.9×10^8 Units/day, to produce an increase in the subject's blood OAS level, relative to the level in the absence of interferon-tau treatment. There is no evidence in Soos to suggest that all of the specifically disclosed interferon-tau doses would produce a measurable increase in human blood OAS levels, nor, more importantly, any evidence to suggest that only specific doses would produce an increase in human OAS levels.

Accordingly, applicants submit that Soos does not provide an inherent teaching of the claimed method and does not render the claimed method obvious. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

IV. Conclusion

In view of the foregoing, the claims pending in the application comply with the requirements of 35 U.S.C. § 112 and patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 838-4402.

Respectfully submitted,

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